

PSJ17 Exh 119



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Document Title: SUSPICIOUS ORDER MONITORING - DEA ORDER
HOLDS



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1. PURPOSE

To specify procedures for reviewing, investigating and releasing TEVA US DEA Order Holds for controlled substances via the ORACLE system and the reporting of Suspicious Orders to the DEA.

2. SCOPE

These procedures apply to the following TEVA Pharmaceuticals personnel All DEA-employees at other locations are considered in scope and part of DEA Compliance.:

	North Wales, PA	New Britain, PA
DEA Compliance & Diversion Operations	X	X
Customer Service	X	

3. SUMMARY OF REVISIONS

1. Reference to "SORDS" changed to "DefOPS"
2. "Pended Orders" definition expanded to clarify that only DEA Compliance personnel determines whether an order is of unusual size, pattern or frequency.
3. VAWD Criteria added
4. 6.1.1 has been clarified

4. REFERENCES

21 CFR 1301.74(b) states that "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

VAWD Criteria for Record Keeping 7. states that "The wholesale distributor has adequate processes in place for monitoring the purchase activity of customers and identifying ordering patterns that identify potential diversion or criminal activity in accordance with state and federal law for controlled substances and "listed chemicals." This requirement also applies to other prescription drugs known by the wholesaler to be subject to diversion or criminal activity, such as non-controlled pain medication, lifestyle drugs, short supply drugs, and drugs with a high potential for diversion."

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5. DEFINITIONS

DEA: Abbreviation for the Drug Enforcement Administration

SOM: Abbreviation for Suspicious Order Monitoring

DefOPS: The Acronym for TEVA's SOM Electronic Monitor System

SUSPICIOUS ORDERS: Includes, but not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

PENDED ORDERS: Orders that have been stopped in real time because they breached Teva's SOM algorithm. "Pended" orders are deemed "on hold" until they are investigated. DEA Compliance personnel are the only employees that can review pended orders to determine whether they are of unusual size, pattern and/or frequency, and approve, or report as suspicious, pended orders for DEA Holds.

SUSPICIOUS ORDER OVERSIGHT TEAM: A team comprised of a representative from DEA Compliance, Customer Service, and Customer Account Management. Certain situations may warrant the addition of other business units at the request and invitation of DEA Compliance.

DNS: Abbreviation for the Do Not Ship List.

6. PROCEDURE

Responsibility

Action

6.1

Electronic Order Monitoring (DefOPS)

DEA Compliance

6.1.1

Controlled substance orders, and selected non-controlled substance orders (e.g., NABP's VAWD Criteria) for all Teva customers are individually analyzed via the DefOPS system which uses internal computerized statistical calculations to determine whether an order should be pended for further manual investigation. The manual investigation will then determine whether an order may be of unusual size, pattern or frequency.

6.1.2 Any order(s) that has exceeded the SOM business rules in DefOPS are electronically pended in ORACLE.

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6.2 Investigative Review of Pended Orders

6.2.1 All pended orders will be initially reviewed by DEA Compliance. The review process may include reviewing the customer's purchase history for the previous 12 months; reviewing the customer's history regarding pended rules, and/or analyzing any other relevant data or information.

6.2.2 If the order is not consistent with the customer's previous order history and there is not a previous explanation from the customer, the DEA Compliance Team will notify Customer Service to contact the customer for clarification about the quantity ordered.

Customer Service

6.2.3 Customer Service will contact the customer to request the reason for the increase/change in ordering pattern. Questions posed by Customer Service to the customer will be "open-ended" and customer accounts will not be guided to provide the "right" answer. Customer responses will be documented.

6.2.4 Customer Service will forward any information received from the customer to the DEA Compliance Team for review.

6.2.5 If a customer does not satisfactorily respond to a Customer Services inquiry, the appropriate Sales Associate will be contacted and instructed to obtain an explanation from the customer. If there is still not a satisfactory response, the order may be cancelled as per 6.4 and 6.5.

6.2.6 If a customer requests that a pended order be canceled without proper explanation, it will be reported to DEA as suspicious if it is a controlled substance or List 1 chemical, and to the relevant state board of pharmacy and FDA for a non-controlled substance.

6.3 Clearing an Order from Hold

DEA Compliance

6.3.1 An order may be released in ORACLE for fulfillment if it meets one or more of the following criteria:

- The order is within previous purchasing history trends.
- The order has not exceeded "all" usual and customary trends.
- Total orders received are not more than 10 percent over their usual and customary limits.
- The customer provides a reasonable explanation for the increase in orders.
- Any other relevant data.

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6.3.2 DEA Compliance will document the reason the order was released in the DefOPS comments field.

6.4 Orders That Cannot Be Cleared / Targeted Site Visits

6.4.1 If an order cannot be cleared of suspicion using the procedures in 6.3, the line item will be brought to the attention of DEA Compliance Management.

6.4.2 DEA Compliance Management will provide guidance on how to proceed based on the evidence gathered to date.

6.4.3 At the direction of DEA Compliance Management, direct communication may be warranted between TEVA and the customer's SOM Subject Matter Experts. This communication is to determine the compliance risks to TEVA of continuing to do business, and if the customer is compliant with all pertinent state and federal statutes and regulations.

6.4.4 If DEA Compliance discovers extraordinary information regarding the customer, advice will be sought from Legal.

6.4.5 If DEA Compliance Management believes that a site visit is needed to best determine the compliance risks to TEVA of continuing to do business, the Suspicious Order Oversight Team will be informed of any and all information regarding the customer and any possible risk.

Suspicious Order Oversight Team

6.4.6 The Suspicious Order Oversight Team will determine if a site visit is warranted. If a site visit is warranted, it will be conducted as per SOP-8280.

6.5 Reporting a Suspicious Order to DEA

6.5.1 Any order that cannot be cleared of suspicion using the procedures in 6.3 will be reported to the DEA as suspicious. DEA Compliance will notify Customer Service Management via email and will request that the line item be cancelled in Oracle, if it has not already been done.

Customer Service

6.5.2 Upon notification from DEA Compliance, Customer Service will cancel the line item and will notify DEA Compliance in writing once completed.

DEA Compliance

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6.5.3 DEA Compliance will notify the Local DEA Field Office in writing of the following within 24 hours of the completion of the investigation:

- date the order was placed;
- name, address and registration number of the customer;
- name, strength and quantity ordered.

The "Suspicious Order Notification Letter" will be sent via overnight mail with a signature receipt.

6.5.4 For a non-controlled substance, DEA Compliance will notify any relevant agency, if applicable, in writing of the following within 24 hours of the completion of the investigation:

- date the order was placed;
- name, address and registration number of the customer;
- name, strength and quantity ordered.

The "Suspicious Order Notification Letter" will be sent via overnight mail with a signature receipt.

6.5.5 Once an order has been reported as suspicious, DEA Compliance Management will conduct a review of the account and if necessary, will recommend a course of action to the Suspicious Order Oversight Team, and document an appropriate resolution to mitigate all compliance risks to TEVA (e.g., monitor the accounts purchases for 6 months, conduct a site visit/audit, terminate the relationship with the customer, or suspend the customer's ability to order one or more of the following: all controlled substances, all listed chemicals, all controlled substances within one or more specific schedules such as CIIIs, or a specific drug code).

6.6 Suspending Shipments / Account Termination

Suspicious Order Oversight Team

6.6.1 The standard the Suspicious Order Oversight Team will use to determine whether to suspend shipments or terminate a customer relationship, is whether it is more likely than not that the customer is permitting controlled substances to be diverted, whether knowingly, or due to possible negligence in complying with its obligations for professional practice. Decisions will be made on a case-by-case basis and will depend upon a full consideration of circumstances, which may include, but is not limited to:

- Ordering patterns of the customer (e.g., mostly high dosage units of hydrocodone as opposed to a wide range of dosage units).
- Product mix (controlled substances compared with non-controlled substances.)

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- Size and frequency of the orders.
- Publicly available information about the customer.
- Other information provided to DEA Compliance by the customer or others.
- Whether the customer has written policies and procedures to detect and prevent diversion including a SOM program that meets DEA requirements.

DEA Compliance

6.6.2

If it is the decision of the Suspicious Order Oversight Team to restrict or terminate a customer's purchasing ability, DEA Compliance will notify A/R Management of that decision in writing. Any such restriction or termination will be documented on the DNS as per SOP-8278.

DEA Compliance

6.6.3

DEA Compliance will make the appropriate changes to the customer's account in the DefOPS system.

6.6.4

If it is the decision of the Suspicious Order Oversight Team to keep a customer open and unrestricted, then the customer may be required to complete certain action item to mediate risk to TEVA and themselves such as: establishing written policies and procedures on anti-diversion, establishing an SOM program that meets DEA requirements, or making changes to its operations and agreeing to maintain those changes.

6.6.5

If the customer refuses to make the necessary changes, TEVA will take appropriate and timely action against the customer to mitigate the compliance risk to TEVA.

6.6.6

DEA Compliance will notify DEA of any suspicious orders, including any action taken to terminate a customer or restrict a customer's ability to order controlled substances or listed chemicals.

6.6.7

DEA Compliance will place on its "Do Not Ship List" any customer that TEVA restricts or terminates their ability to order controlled substances or listed chemicals.

6.7

Re-Establishing a Closed Account

6.7.1

See SOP-8279, Customer Due Diligence, 6.4.

6.8

SOM Record Keeping

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- 6.8.1 An electronic log will be maintained of all pending/released orders that contains the following information:
- Order Number
 - Order Item (NDC Number)
 - Item Description
 - Quantity
 - Bill to Customer
 - Extended Price
 - Ship to Address
 - Ship to Location (Ship to Number)
 - Explanation for Order Release
 - Order Release Date
- 6.8.2 The electronic log referenced in 6.8.1 will be reviewed monthly for trends, patterns, appropriateness, and/or any other reason deemed necessary.
- 6.8.3 Documentation will be kept for all orders that require a site visit or have been reported to DEA, or if the customer's purchasing abilities have been restricted. A file will be maintained and held by DEA Compliance for a period 2 years from the date the investigation was closed.
- 6.8.4 An electronic log titled "Do Not Ship List" will be maintained by DEA Compliance, per SOP-8278, Do Not Ship List.

7. ATTACHMENTS

Title 21, Code of Federal Regulations, Section 1301.74(b);

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QUIZ

1. TEVA's electronic order monitoring system (DefOPS) uses statistical calculations to identify potential suspicious orders of unusual size, pattern or frequency.

TRUE or FALSE
2. Once an order has been identified by DefOPS and "pending", it can only be released by a member of Customer Service.

TRUE or FALSE
3. A member of DEA Compliance determines whether an order is suspicious.

TRUE or FALSE
4. Only controlled substances are monitored by DefOPS.

TRUE or FALSE

SIGNATURES

Employee (print name):	
Employee (signature):	Date:
<i>Quiz answers checked for correctness. All questions incorrectly answered were discussed with the employee and understood.</i>	
Instructor (signature):	Date:

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